

# In The United States Court of Federal Claims

No. 00-590V

(Filed Under Seal: March 9, 2016)

Reissued: March 25, 2016<sup>1</sup>

DWAYNE COZART AND MICHELE  
HAMILTON, as representatives of the  
Estate of C.A.C.

Petitioners,

v.

SECRETARY OF HEALTH AND  
HUMAN SERVICES,

Respondent.

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Vaccine case; Motion for Review; Hepatitis-  
B vaccination; Standard of review; *Althen*;  
Failure to establish causation; Motion for  
Review denied.

## OPINION

*Ronald Craig Homer*, Conway, Homer & Chin-Chaplin, P.C., Boston, MA, for petitioners.

*Ryan Daniel Pyles*, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

### SMITH, Senior Judge:

Petitioners, Dwayne Cozart and Michele Hamilton, as representatives of the estate of their son, C.A.C., seek review of a decision issued by Chief Special Master Nora Beth Dorsey denying their petition for vaccine injury compensation. Petitioners brought this action pursuant

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<sup>1</sup> An unredacted version of this opinion was issued under seal on March 9, 2016. The parties were given an opportunity to propose redactions, but no such proposals were made. Nevertheless, the court has incorporated some minor changes into this opinion.

to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 et seq. (2012), alleging that C.A.C. died from Sudden Infant Death Syndrome (“SIDS”) that was caused by the hepatitis-B (“Hep B”), diphtheria-tetanus-acellular-pertussis (“DTaP”), inactive polio vaccine (“IPV”), and haemophilus influenza type b (“Hib”) vaccines that he received at his two month well-child visit. Initially, the Chief Special Master denied compensation, finding that C.A.C.’s SIDS was not caused by the vaccinations. *Cozart & Hamilton v. Sec’y of Health & Human Servs.*, 2015 WL 6746616 (Fed. Cl. Spec. Mstr. Oct. 15, 2015) (“*Cozart*”). Petitioners now move for review of this decision. For the reasons that follow, the court **DENIES** their motion.

## I. BACKGROUND

A brief recitation of the facts provides necessary context.<sup>2</sup>

C.A.C. was born on August 17, 1998. At his two week well-child visit to his pediatrician, he was noted to be developing normally. C.A.C. had an untreated bumpy rash from August 25, 1998 to September 29, 1998, which the pediatrician concluded was likely eczema.

On October 19, 1998, C.A.C. attended his two month well-child visit to the pediatrician. At approximately 10:15 a.m. that same day, C.A.C. received his Hep B, DTaP, IPV, and Hib vaccines. He was then taken to his babysitter’s house, and the babysitter put him down for a nap. At 2:57 p.m., emergency medical services (“EMS”) were dispatched to the babysitter’s home because C.A.C. was unresponsive. Upon arrival, C.A.C. was pulseless and apneic. EMS performed cardiopulmonary resuscitation (“CPR”), and C.A.C. was intubated and given epinephrine.

C.A.C. was then taken to the Charlton Methodist Hospital. Upon arrival at approximately 3:30 p.m., he had no pulse and was asystolic. The endotracheal tube was removed from his esophagus and placed in his trachea, and CPR was continued. C.A.C. also received atropine and epinephrine.

At the hospital, Dr. Joe Tsou documented C.A.C.’s “history of present illness,” in which he wrote that the child presented to the Emergency Department (“ED”) with CPR in progress after being found unresponsive at the babysitter’s home. Dr. Tsou also noted that C.A.C. received immunizations earlier that morning at the pediatrician’s office, after which his mother gave him Tylenol and left him at the babysitter’s home. Dr. Tsou documented the infant’s rectal temperature as 94.7 degrees, indicating that “significant time had elapsed since the time of arrest.” Dr. Tsou also performed a physician exam, noting “coffee ground vomitus around [the] mouth,” congested chest, distended abdomen, and paleness. C.A.C. was pronounced dead at 3:47 p.m., after resuscitative efforts were not successful. The case was then reported to the medical examiner’s office.

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<sup>2</sup> As the basic facts here have not changed significantly, the court’s recitation of the background facts here draws from the Chief Special Master’s earlier opinion in *Cozart*.

The medical examiner and pathologist in this case was Dr. Lauri S. Holley of the Dallas County Medical Office, Dallas County Institute of Forensic Sciences. She performed an autopsy on C.A.C. on October 20, 1998. The external examination revealed “posterior lividity<sup>3</sup> [that was] partially fixed” and “lividity of the right side of the face with blanching over the pressure areas.” C.A.C. also had lividity visible on the right ear and neck. The internal examination revealed petechiae<sup>4</sup> of the epicardium, petechiae of the pleural lung surfaces, and moderately congested parenchyma of the lung. A chest x-ray showed a right pneumothorax.<sup>5</sup> A microscopic examination of the lung tissue showed atelectasis<sup>6</sup> of tissue from the right lung, and “intra-alveolar hemorrhage in the right middle and left upper lobes.” A microscopic examination of the thymus revealed “minimal focal involution” and an increase in “Hassall’s corpuscles.” The “[h]istologic sections of [the] medulla at multiple levels reveal[ed] scant arcuate nuclei neurons bilaterally.” Dr. Holley noted that “[a]rcuate nucleus hypoplasia has been reported in association with infants dying of SIDS.” The medical examiner concluded that the C.A.C.’s death should be classified as SIDS. She reasoned that “[t]his category is used when complete autopsy, investigation, and additional studies fail to yield a definite cause of death. Although there was recent immunization, a connection to the death could not be established.”

Petitioners filed their vaccine petition on October 2, 2000, pursuant to the Vaccine Act, and alleging that C.A.C. had “an adverse reaction to [his October 19, 1998 vaccinations], which resulted in his death....” *See* Petition at 1. On October 24, 2011, petitioners filed an amended petition setting forth additional factual support for their claim.<sup>7</sup> *See* Amended Petition. Petitioners filed the expert report of Dr. Douglas C. Miller,<sup>8</sup> a neuropathologist, on August 6,

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<sup>3</sup> Lividity is defined as “the quality of being livid; discoloration, as of dependent parts, by the gravitation of the blood.” *Dorland’s Illustrated Medical Dictionary* 1069 (32nd ed. 2012) (“*Dorland’s*”).

<sup>4</sup> Petechia (plural petechiae) is defined as “a pinpoint, nonraised, perfectly round, purplish red spot caused by intradermal or submucous hemorrhage.” *Dorland’s* at 1422.

<sup>5</sup> Pneumothorax is defined as “an accumulation of air or gas in the pleural space.” *Dorland’s* at 1476.

<sup>6</sup> Atelectasis is the “incomplete expansion of a lung or a portion of the lung.” *Dorland’s* at 171.

<sup>7</sup> This case was part of an omnibus proceeding in which all participating petitioners alleged that thimerosal in pediatric vaccines caused or contributed to death. *See* Order dated Sept. 27, 2011 (indicating that this case was part of the omnibus proceeding). On November 23, 2010, a decision was entered denying entitlement in the test case proceeding, *Kolakowski v. Sec’y of Health & Human Servs.*, No 99-625V, 2010 WL 5672753 (Fed. Cl. Spec. Mstr. Nov. 23, 2010).

<sup>8</sup> Dr. Miller received his medical degree from the University of Miami, School of Medicine in 1978. Curriculum Vitae of Dr. Douglas C. Miller, Pet. Ex. 22 at 1. He has a Ph.D. in physiology and biophysics from the University of Miami. *Id.* He also was a resident at Massachusetts General Hospital from 1980-84, focusing in anatomic pathology and

2012. In addition to the expert report, petitioners filed Dr. Miller's curriculum vitae and seven exhibits of medical literature referenced in Dr. Miller's report.

On September 26, 2012, respondent filed a motion for summary judgment, arguing that "on the current record, there is a lack of evidence as a matter of law for the Court to find that petitioners are entitled to compensation under the terms of the [Vaccine] Act," and that the petition must be dismissed. *See* Respondent's Motion for Summary Judgment ("MSJ") at 8, 12. On October 15, 2012, petitioners filed an opposition to respondent's motion for summary judgment, contending that "respondent has not shown that a 'genuine issue as to a material fact' does not exist, and therefore, [respondent's MSJ] must be denied." *See* Petitioners' Opposition to Respondent's Motion for Summary Judgment ("Opp. To MSJ") at 8. Chief Special Master Dorsey denied respondent's motion for summary judgment on February 12, 2013, finding that summary judgment would be inappropriate because petitioners' expert reports raised issues of fact as to causation. *See* Order Denying Respondent's Motion for Summary Judgment at 4.

Respondent then filed an expert report from Dr. Hart G. W. Lidov, a neuropathologist, on April 30, 2013.<sup>9</sup> Respondent filed a second expert report from Dr. Christine McCusker, an immunologist, on June 21, 2013.<sup>10</sup> Subsequently, petitioners filed an expert report from Dr. James Oleske, an immunologist, on December 11, 2013.<sup>11</sup>

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neuropathology. *Id.* He most recently serves as a clinical professor of pathology and anatomical science at the University of Missouri, School of Medicine, and he is the program director of pathology residency. *Id.* at 3. He is also an associate medical examiner for Boone, Callaway, and Greene Counties in Missouri. *Id.*

<sup>9</sup> Dr. Lidov received a Ph.D. from Johns Hopkins University 1980 and a medical degree in 1982. Curriculum Vitae of Dr. Hart G. W. Lidov, Resp. Ex. B at 1. He was a resident in pediatrics and neurology at Massachusetts General Hospital and a neuropathology and anatomic pathology resident at Brigham and Women's Hospital from 1983-91. *Id.* He has a special qualification in child neurology from the American Board of Psychiatry and Neuropathology. *Id.* at 2. He is currently a staff neurologist at Children's Hospital in Boston, associate neuropathologist at Brigham and Women's Hospital, and consultant in neuropathology at Beth Israel Deaconess Medical Center. *Id.* at 3.

<sup>10</sup> Dr. McCusker earned a Master's of Science at McMaster University in 1988 and a medical degree at McMaster University in Hamilton, Ontario (Canada) in 1993. Transcript of Proceedings, September 25-26, 2014, page 121 (hereinafter "Tr. \_\_\_\_"). Her residency training in pediatrics was at Montreal Children's Hospital, McGill University. *Id.* She was a clinical fellow in allergy and immunology at McGill University from 1996-99. Curriculum Vitae of Dr. Christine McCusker, Resp. Ex. D at 1. She is board certified in pediatrics and allergy and immunology, and she treats pediatric patients at an allergy clinic. Tr. 122-23. She teaches medical students immunology, dermatology, and malignant hematology. *Id.* at 123.

<sup>11</sup> Dr. Oleske received his medical degree from Seton Hall Medical School (now Rutgers New Jersey Medical School) in 1971. Tr. 5. He also has a Master's degree in Public Health from Columbia University. *Id.* He is licensed to practice in New Jersey with specialties in

An entitlement hearing was held in Washington, DC on September 25 and 26, 2014. At the conclusion of the hearing, and after the experts testified, Chief Special Master Dorsey encouraged the parties to discuss informal resolution. On December 5, 2014, the parties filed a joint status report indicating that they were unable to resolve the case, so Chief Special Master Dorsey held an additional status conference in an attempt to provide the parties with assistance in resolving the case. Chief Special Master Dorsey then requested that the parties make one final attempt at informal resolution. *See* Order dated January 7, 2015, at 1. Those efforts were unsuccessful.

On June 30, 2015, Chief Special Master Dorsey issued a decision denying petitioners' claim and finding that petitioners were not entitled to compensation because they failed to provide by a preponderance of the evidence that the vaccinations C.A.C. received on October 19, 1998, caused his death. Petitioners filed a Motion for Reconsideration of the original decision on July 21, 2015. Chief Special Master Dorsey granted that motion to the extent that it vacated the Original Decision. On August 12, 2015, respondent filed a response to the Motion for Reconsideration, and, on August 26, 2015, petitioners filed a reply brief. Chief Special Master Dorsey found that petitioners failed to demonstrate, by a preponderance of the evidence, that the vaccinations act similarly to other exogenous stressors identified by the Triple Risk Model.<sup>12</sup> On October 15, 2015, Chief Special Master Dorsey denied petitioners' Motion for Reconsideration and reinstated the original decision.

On November 16, 2015, petitioners filed a Motion for Review ("MFR") of the Chief Special Master's decision. Respondent filed a response to petitioners' Motion for Review ("Resp. to MFR") on December 16, 2015. Argument on this motion is deemed unnecessary, and the Motion for Review is now ripe for decision.

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pediatrics and diagnostic laboratory immunology. *See* Curriculum Vitae of Dr. James Oleske, Pet. Ex. 48 at 2. He is certified by the American Board of Pediatrics and the American Board of Allergy and Immunology. Tr. 7. He worked with the Brighton Group, focusing on issues of vaccine safety. *Id.* He currently serves as the Director of the Division of Allergy, Immunology, and Infectious Diseases and Pediatric Palliative Care at Rutgers New Jersey Medical School. *Id.* at 5.

<sup>12</sup> Hannah C. Kinney, et al., *Risk Factor Changes for Sudden Infant Death Syndrome After Initiation of Back-to-Sleep Campaign*, 129 *Pediatrics* 630, 630-638 (2012); the Triple Risk Model is a theory for SIDS, in which SIDS occurs when three factors are present simultaneously. The first factor is an underlying vulnerability in the infant; the second, a critical developmental period; and the third, an exogenous stressor. Underlying vulnerabilities, or internal risk factors, include, for example, brain abnormalities affecting blood pressure, heart rate, and respiration. The critical development period is typically one to six months old, when the infant's cardiorespiratory protective mechanisms are not fully developed. The exogenous stressor, or extrinsic risk factor, can include, for example infection, illness, sleep position, or sleep environment.

## II. DISCUSSION

Under the Vaccine Act, this court may review a special master's decision upon the timely request of either party. *See* 42 U.S.C. § 300aa-12(e)(1)-(2). In that instance, the court may: “(A) uphold the findings of fact and conclusions of law..., (B) set aside any findings of fact or conclusion of law...found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law..., or, (C) remand the petition to the special master for further action in accordance with the court's direction.” *Id.* at § 300aa-12(e)(2)(A)-(C). Findings of fact and discretionary rulings are reviewed under an “arbitrary and capricious” standard, while legal conclusions are reviewed *de novo*. *Munn v. Sec’y of Health & Human Servs.*, 970 F.2d 863, 870 n. 10 (Fed. Cir. 1992); *see also Doyle ex rel. Doyle v. Sec’y of Health & Human Servs.*, 92 Fed. Cl. 1, 5 (2010).

*Althen* provides the evidentiary burden for petitioners attempting to succeed in a vaccine petition based on causation. *See generally Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). In order to prove causation-in-fact, a petitioner must

show by preponderant evidence that the vaccination brought about [petitioner's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

*Id.* at 1278. In order to succeed, petitioners must provide a “reputable medical or scientific explanation” for their claim. *Id.*

Within this framework, petitioners make six numbered objections to the October 15, 2015 decision. First, they assert that it was arbitrary, capricious, and an abuse of discretion for the Chief Special Master to ignore relevant evidence supporting petitioners' relevant medical theory. Second, they argue that the Chief Special Master's requirement of direct proof of inflammation elevated petitioners' burden with regard to *Althen* prong two and is not in accordance with the law. Third, they assert that it was arbitrary, capricious, and an abuse of discretion for the Chief Special Master to ignore relevant evidence with regard to *Althen* prong two. Fourth, they posit that it was arbitrary, capricious, and an abuse of discretion for the Chief Special Master to determine that petitioners' theory of causation relied on the occurrence of a cytokine storm. Fifth, they assert that it was arbitrary, capricious, and an abuse of discretion for the Chief Special Master to determine that C.A.C. was in a prone position at the time of death. Finally, petitioners argue that the Chief Special Master's decision is not in accordance with the law because she elevated petitioners' burden of proof with regard to *Althen* prong one.

### A. Petitioners' Relevant Medical Theory

Petitioners' assert that it was arbitrary, capricious, and an abuse of discretion for the Chief Special Master to ignore relevant evidence supporting their medical theory. In

determining whether a special master's finding of fact is arbitrary and capricious, this court must look to plausibility, not to whether it is supported by a preponderance of the evidence. As long as the finding of fact is "based on evidence in the record that [is] not wholly implausible, [this court is] compelled to uphold the finding as not being arbitrary or capricious." *Porter v. Sec'y of Health & Human Servs.*, 663F.3d 1242, 1249 (Fed. Cir. 2012) (quoting *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010)). This is similar to the clearly erroneous standard of factual review.

Petitioners argue that Chief Special Master Dorsey incorrectly assessed the importance of the Froen article.<sup>13</sup> MFR at 9. Petitioners' counsel initially points out that the Froen article was not extensively discussed by either Dr. Miller or Dr. Oleske, but he then proceeds to argue for its significance. Essentially, petitioners highlight the effect of cytokines on autoresuscitation after apnea, as studied in the Froen article. They posit that the cytokine response described by Froen has important implications for SIDS. *Id.* at 10-11. Petitioners then proceed to cite to a number of exhibits provided prior to Chief Special Master Dorsey's Decision, asserting their scientific importance in likening vaccines to infections for the purposes of SIDS deaths. *Id.* at 11-12. All of these articles were considered by Chief Special Master Dorsey, and she found them unpersuasive.

In addition to the Froen article, petitioners assert that Chief Special Master Dorsey "ignored thirty (30) additional articles used by Dr. Miller and Dr. Oleske to support their opinion." *Id.* at 9 (emphasis in original). Failing to cite to each individual piece of evidence is not the equivalent of ignoring evidence. A special master is not required to cite to every piece of evidence so long as she "conduct[s] a detailed review of the testimony, medical records, and medical literature." *Doe 11 v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1355 (Fed. Cir. 2010). As previously stated, in determining whether a finding of fact was arbitrary and capricious, the court must look to whether said finding of fact was "wholly implausible." *Porter*, 663F.3d at 1249 (quoting *Cedillo*, 617 F.3d at 1338). Chief Special Master Dorsey based her finding that vaccines are not an exogenous trigger in SIDS deaths on the extensive testimony and medical evidence provided by both petitioners and respondent. Her determination that the testimony and evidence provided by respondent was more persuasive than the testimony and evidence provided by petitioners was a finding of fact. This court does not deem that finding of fact to be wholly implausible, and thus this court is compelled to uphold it as not being arbitrary or capricious.

## **B. Requirement of Direct Proof of Inflammation**

Petitioners argue that Chief Special Master Dorsey required that they provide conclusive scientific proof of an inflammatory response to succeed on their petition. The basis for this argument is in the statement that "[i]f Dr. Oleske is correct and cytokines caused a pro-

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<sup>13</sup> Froen JF, et al., Adverse effects of nicotine and interleukin-1 $\beta$  on autoresuscitation after apnea in piglets: implications for sudden infant death syndrome, *PEDIATRICS*, 105:E52 (2000).

inflammatory response, then it is likely that there would be evidence of inflammation in the brain, but Dr. Miller testified that there was no such evidence.” Tr. 354. This allegation that Chief Special Master Dorsey was requiring conclusive scientific evidence is incorrect. Rather, she was merely considering the evidence proffered by petitioners. Dr. Oleske testified that an inflammatory response to the foreign antigen would be triggered by the vaccination within three to six hours. *Id.* at 73-74. This would lead to a number of symptoms, including fever and increased heart rate. *Id.* at 74. Dr. Oleske also testified that, in a previous SIDS case in which he provided expert testimony, the infant exhibited unusual behavior, irritability, loss of appetite, and redness at the site of the vaccination. *Id.* at 40. He also testified that C.A.C. did not exhibit any of these symptoms and his inflammatory response was silent. *Id.*

Dr. Oleske’s theory that vaccines are an extrinsic factor in SIDS deaths heavily relies on the release of pro-inflammatory cytokines. Dec. at 11; Tr. 85. Chief Special Master Dorsey considers this theory in depth, but finds that, even if this theory was supported by the medical community at large, there was no evidence of a pro-inflammatory response in this case. Dec. at 19. In fact, petitioners’ expert, Dr. Miller, testified that there was “no description of any inflammation in the pathology [autopsy] report.” Tr. 354. Dr. Miller goes further, testifying that “there was no evidence that the vaccines caused any injury based on the examination of C.A.C.’s organs at autopsy.” *Id.* at 347.

Petitioners provide a theory to support vaccinations as an external stressor which directly depends upon the creation of a pro-inflammatory response. In looking at the medical evidence of record and expert testimony, Chief Special Master Dorsey was unable to find any evidence that C.A.C. experienced a pro-inflammatory response. As Dr. Oleske’s theory directly relies on the presence of a pro-inflammatory response, and none was noted in C.A.C., it would follow that Dr. Oleske’s theory that C.A.C. died as a result of his October 19, 1998, vaccines is unsupported. Chief Special Master Dorsey did not raise petitioners’ burden of proof by finding that C.A.C. did not exhibit a pro-inflammatory response, as that response was an important part of the theory set forth by petitioners.

### **C. *Althen* Prong Two**

In order to succeed on prong two of *Althen*, petitioners must prove by a preponderance of the evidence that there is “a logical sequence of cause and effect showing that vaccination was the reason for the injury.” *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1324 (Fed. Cir. 2006) (quoting *Althen*, 418 F.3d at 1278). Petitioners object to the finding that there was no direct or circumstantial evidence of cytokine involvement in C.A.C.’s brain. In their Motion for Review, petitioners specifically assert that they “*did* submit a great deal of circumstantial evidence that [cytokine involvement] occurs in SIDS and was likely the cause of death.” MFR at 21-22 (emphasis in original). They point to testimony by Dr. Miller that “certain cytokines can cross the blood brain barrier.” *Id.* at 22.

While a finding of causation “must be supported by a sound and reliable medical or scientific explanation,” causation “can be found in vaccine cases...without detailed medical and

scientific exposition on the biological mechanisms.” *Knudsen v. Sec’y of the Dep’t of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). However, petitioners must still provide a “reputable medical or scientific explanation” for their claim. *Althen*, 418 F.3d at 1278. Here, both Dr. Miller and Dr. Oleske point to the importance of cytokines in vaccine induced deaths. *See generally* Dec. Dr. Miller testified that “there is no way to verify the presence of cytokines or to test for them.” Tr. 325. Throughout the testimony and the medical evidence presented in this case, petitioners’ experts have routinely indicated that factors such as fever or inflammation often indicate an increase in cytokines following illness or a vaccination. Dec. at 18-20. However, Dr. Oleske stated that “C.A.C. did not exhibit these symptoms and his inflammatory response was silent.” *Id.* at 19; Tr. 40. Similarly, Dr. Miller testified that “there was no evidence that the vaccines caused any injury based on the examination of C.A.C.’s organs at autopsy.” Dec. at 19-20; Tr. 347. Chief Special Master Dorsey considered all of this evidence offered by petitioners’ experts in her decision. She did not, as petitioners assert, “cho[o]se to ignore [relevant cytokine] evidence.” MFR at 22.

Additionally, “special masters have broad authority in building a record for decision in vaccine cases and enjoy ‘flexible and informal standards of admissibility of evidence.’” *Hunt v. Sec’y of Health & Human Servs.*, 123 Fed. Cl. 509, 519 (2015) (citing *Davis v. Sec’y of Health & Human Servs.*, 94 Fed. Cl. 53, 65 (2010), *aff’d*, 420 F.Appx. 973 (Fed. Cir. 2011) (quoting 42 U.S.C. § 300aa–12(d)(2)(B))). Special masters need not discuss every scintilla of evidence when issuing a decision. As such, “[t]his Court will not substitute its judgment for that of the Special Master when the Special Master considered all of the *pertinent* evidence, including many of the particulars cited by Petitioner.” *Vaughan on Behalf of A.H. v. United States*, 107 Fed. Cl. 212, 220 (2012) (emphasis added). Thus, Chief Special Master Dorsey did not act in a manner arbitrary and capricious in her decision not to discuss every item of cytokine evidence presented by petitioners.

#### **D. Occurrence of a Cytokine Storm**

In their third objection, petitioners argue that the evidence submitted supports the theory that cytokines played an important role in C.A.C.’s death. Then, in their fourth objection, they purport to have never indicated that a cytokine storm in any way played a role in C.A.C.’s death. In arguing these two objections, petitioners are drawing a very thin distinction between an increase in cytokines resulting from a vaccination and a cytokine storm.<sup>14</sup> Petitioners’ medical experts testified about both an upswing in cytokine activity and a cytokine storm, and Chief Special Master Dorsey addressed both of these divergent theories for how a vaccine may lead to a SIDS death. Petitioners argue that Chief Special Master Dorsey determined that their theory of causation relies on said cytokine storm. MFR at 23. This interpretation of the Decision is incorrect. Chief Special Master Dorsey simply addressed one explanation for the theory that the

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<sup>14</sup> A “cytokine storm” is defined as a “profound systemic oversecretion of cytokines.” *See* Institute of Medicine, *Adverse Effects of Vaccines-Evidence and Causality* 75 (2012). The process results in “local tissue and organ damage, and systemic symptoms.” *Id.*

October 19, 1998 vaccinations caused C.A.C.'s death, which she has done alongside discussions of other theories proffered by petitioners.

Chief Special Master Dorsey discussed cytokine involvement in her discussion of both prong one and prong two of *Althen*. In her evaluation of the evidence for *Althen* prong one, Chief Special Master Dorsey did not discuss a cytokine storm. She did, however, discuss the lack of evidence on whether cytokines act to cause pathology or signal the occurrence of pathology. Dec. at 18.

In discussing *Althen* prong two, Chief Special Master Dorsey discussed both the cytokine interaction with the brain and the cytokine storm. Primarily, she discussed the lack of evidence to support the theory that "peripheral cytokines released in response to the vaccines... communicated with the central nervous system to invoke an abnormal brain response in the manner described by Dr. Oleske and Dr. Miller." *Id.* at 22-23. She also cited to evidence of a lack of pro-inflammatory response in C.A.C.'s brain. Tr. 354.

Additionally, Chief Special Master Dorsey found no evidence of a fever, illness, or clinical sign or symptom typically present with the release of cytokines. She determined that, based on evidence and medical testimony provided by petitioners, cytokines likely did not have a causal role in C.A.C.'s SIDS death. Dec. at 23. Petitioners agree that "Dr. Oleske used the terminology 'cytokine storm,' at [the] hearing." MFR at 24. They then posit that "Dr. Oleske clearly did not mean cytokine storm in the traditional sense and his economy of language should not be used to import a different meaning to his testimony." *Id.* at 24-25. Whether or not Dr. Oleske's meaning of "cytokine storm" was clear, Chief Special Master Dorsey's finding that a cytokine storm did not occur was directly supported by the testimonial evidence from Dr. McCusker. Dr. McCusker testified that patients who develop a cytokine storm as experiencing a "massive, uncontrolled pulmonary inflammation as a result of viral-induced cytokine storm in the airways." Tr. 255. It is not unreasonable for Chief Special Master Dorsey to discuss a "cytokine storm" as a possible explanation for petitioners' theory that vaccines triggered C.A.C.'s death when petitioners themselves raised the issue. Additionally, her discussion of a cytokine storm, as well as her finding that a cytokine storm did not occur, does not support petitioners' theory of causation. As such, this court must find that her inclusion of that discussion, as well as her determination that a cytokine storm did not exist, is not arbitrary or capricious. *Porter*, 663 F.3d at 1249. Therefore, this court is compelled to uphold that finding.

#### **E. Prone Position at the Time of Death**

The Chief Special Master found that C.A.C. was "lying on his face, either in the prone or the side position, both of which are strongly associated with SIDS." Dec. at 23. Petitioners assert that it was arbitrary, capricious, and an abuse of discretion for the Chief Special Master to determine that C.A.C. was lying in the prone position at the time of death. Petitioners base their argument on a notation in the record indicating lividity on the back and right ear and neck with blanching. Pet. Ex. 12 at 17. Petitioners attempt to conclude that the absence of front lividity would indicate that C.A.C. could only have been lying in the supine position. MFR at 27.

Petitioners then argue that, if the lividity pattern only supports a finding that C.A.C. was in the supine position, the Chief Special Master's finding that he was in the prone position was arbitrary, capricious, and an abuse of discretion.

In arguing that C.A.C. could only have been lying in the supine position at the time of death, petitioners completely ignore other relevant facts and expert testimony by both respondent's and petitioners' medical experts. Significantly, C.A.C. was "noted facedown by EMS." Dec. at 4, 23 (citing Pet. Ex. 12 at 31). Petitioners argue that this was merely a statement made by EMS to the nurse, and that neither the nurse nor EMS personally witnessed the death scene. However, Dr. McCusker explained that this notation is particularly reliable, as sleep position is "one of the first questions that is asked during an investigation into [a SIDS death]." *Id.* at 21. Dr. McCusker further explained that when a baby sleeps in the supine position, the baby's face may be turned to the side, but pressure would not have been exerted to the side of the face in a way that could have caused the lividity present in C.A.C.'s case. However, if the baby was lying either on its side or in the prone position, the pressure on the baby's face from that position could have reasonably caused the lividity and blanching noted here.<sup>15</sup> Furthermore, petitioners' own medical expert, Dr. Miller, also conceded that the lividity pattern could be explained by C.A.C. being in a prone position at the time of death. *Id.* at 20. This directly contradicts petitioners' argument that "Dr. Miller testified that [C.A.C.'s] lividity pattern was *only* consistent with C.A.C. being on his back when he died." MFR at 27 (emphasis in original).

C.A.C.'s sleep position is relevant in this case, though not outcome determinative. Petitioners are correct in their assessment that the only external stressor specifically identified by Chief Special Master Dorsey was that C.A.C. was sleeping in the prone position. *Id.* at 30. Petitioners essentially argue that, if C.A.C. was not sleeping in the prone position, the only other possible external stressor are his October 19, 1998 vaccinations. Even if petitioners could prove that C.A.C. was sleeping in the supine position, absence of evidence is not evidence. Petitioners failed to provide, by a preponderance of the evidence, proof that the vaccines caused C.A.C.'s death, and they cannot use the absence of alternative explanations to support their theory. *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1149 (Fed. Cir. 1992).

As previously stated, in determining whether a special master's finding of fact is arbitrary and capricious, this court must look to plausibility, not to whether it is supported by a preponderance of the evidence. As long as the finding of fact is "based on evidence in the record that [is] not wholly implausible, [this court is] compelled to uphold the finding as not being arbitrary or capricious." *Porter*, 663F.3d at 1249 (quoting *Cedillo*, 617 F.3d at 1338). The lividity pattern and expert testimony both support a finding that C.A.C. could have been lying in the prone position. Therefore, that finding is not "wholly implausible," and this court must not treat it as arbitrary and capricious. *Id.*

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<sup>15</sup> Chief Special Master Dorsey does note that Dr. McCusker is not an expert on lividity. She further notes that, even if Dr. McCusker's testimony had been excluded on this issue, the testimony is not outcome determinative, and her decision would have remained the same.

## F. *Althen* Prong One

Petitioners argue that Chief Special Master Dorsey increased their burden of proof with regard to *Althen* prong one. They assert that by “requiring evidence specifically implicating vaccines...[she effectively required petitioners to] submit epidemiological evidence *scientifically* proving vaccination as an extrinsic risk factor for SIDS.” MFR at 31 (emphasis in original). In her assessment of *Althen* prong one, Chief Special Master Dorsey sought a “sound and reliable medical or scientific explanation” in determining whether petitioners’ theory of causation could be proved by a preponderance of the evidence. *Knudsen*, 35 F.3d at 548. Petitioners object to this standard and seek application of the *Contreras* standard, which merely requires a “plausible medical theory” to meet *Althen* prong one. *Contreras v. Sec’y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015). This court rejects the application of the *Contreras* standard in this case.

The Federal Circuit in *Moberly v. Sec’y of Health & Human Servs.* held that “[a]lthough a Vaccine Act claimant is not required to present proof of causation to the level of scientific certainty, the special master is entitled to require some indicia of reliability to support the assertion of the expert witness.” 592 F.3d 1315, 1324 (Fed. Cir. 2010). Petitioners read this to mean that plausibility is enough to support a theory of causation. This court disagrees. *Althen* requires that petitioners must provide a “reputable medical or scientific explanation” for their claim.” *Althen*, 418 F.3d at 1278. “The determination of whether a proffered theory of causation is ‘reputable’ may ‘involve an assessment of the relevant scientific data.’” *Hazlehurst ex rel. Hazlehurst v. Sec’y of Health & Human Servs.*, 88 Fed. Cl. 473, 479 (2009) (quoting *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009)). Chief Special Master Dorsey assessed the “relevant scientific data” and determined that petitioners did not prove, by a preponderance of the evidence, that C.A.C.’s October 19, 1998 vaccinations had a causal connection to his SIDS death. “[R]eversible error will be extremely difficult to demonstrate’ where the special master ‘has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.’” *Porter*, 663 F.3d at 1253-54 (quoting *Hines v. Sec’y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)); see also *Lombardi v. Sec’y of Health & Human Servs.*, 656 F.3d at 1343, 1353 (Fed. Cir. 2010). Such is the case here.

Even if this court were to apply the standard set forth in *Contreras*, petitioners still have not met their burden under *Althen* prong one. Petitioners argue that “*Althen* prong one merely demands a threshold level of scientific reliability for an expert’s proposed biological mechanism which can cause a vaccine injury.” MFR at 34 (citing *Contreras*, 121 Fed. Cl. at 245). Petitioners’ own expert, Dr. Miller, testified that “he did not know anyone else other than Dr. Olseke” who has identified vaccines as an external risk factor applicable to the Triple Risk Model. Dec. at 13. Plausibility alone, without medical or scientific support, is not enough to prove a theory of causation, and Chief Special Master Dorsey has not raised petitioners’ burden of proof by applying the standard of requiring a sound and reliable medical or scientific explanation.

### III. CONCLUSION

This court understands and appreciates the pain inherent in losing a child. Unfortunately, petitioners were unable to meet their burden of proving that C.A.C.'s October 19, 1998 vaccinations lead to his untimely SIDS death. For the foregoing reasons, the court **DENIES** petitioners' motion for review.<sup>16</sup>

**IT IS SO ORDERED.**

s/ *Loren A. Smith*

Loren A. Smith,  
Senior Judge

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<sup>16</sup> This opinion shall be unsealed, as issued, after March 23, 2016, unless the parties, pursuant to Vaccine Rule 18(b), identify protected and/or privileged materials subject to redaction prior to that date. Said materials shall be identified with specificity, both in terms of the language to be redacted and the reasons therefor.